

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

JAVIER SEGADO FERRAN : Confirmation No.: 1427

Serial No.: 10/517,110 : Art Unit: 1618

Filing Date: December 7, 2004 : Examiner: H.S. Ahmed

For: **ORALLY DISINTEGRATING TABLETS AND
PROCESS FOR OBTAINING THEM**

RESPONSE

Mail Stop: Response
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

June 19, 2008

SIR:

In response to a restriction requirement dated February 19, 2008, Applicant elects, with traverse, the claims of Group I, that is, Claims 1-4 and 9, drawn to a tablet for oral administration that disintegrates quickly.

Withdrawal of the restriction requirement is respectfully requested. According to Chapter V, International Phase of the PCT Applicant's Guide § 42-218, paragraph 138, it is stated that:

"An International application which complies with the unity of invention requirements laid down in Rule 13 must be accepted by all the designated and elected Offices, since Art.

27(1) does not allow any national law (as defined in Art. 2(x)) to require compliance with requirements relating to the contents of the international application different from or additional to those provided for in the PCT.”

With regard to the present case, the International Searching Authority has generated an International Search Report (ISR) for all of Claims 1 to 14 without determining that the present invention does not fulfill the “unity requirement”. See the copy of the ISR attached herewith. In addition, the International Preliminary Examination Authority considered the requirement of “unity of invention”. See the copy of the International Preliminary Examination Report (IPER) attached hereto. Since neither authority indicated that there was a unity of invention issue, it is inconsistent with Paragraph 138, cited above, for the USPTO to now make a restriction requirement with regard to the same Claims 1 to 14.

The Examiner mentions PCT Publication No. WO 01/12161 in his reasoning for the restriction requirement. Applicant points out that both the International Searching Authority and the International Preliminary Examination Authority reference this PCT publication. None of the Authorities found lack of unity by the presence of this PCT publication. Although a lack of unity of invention may arise after a search of prior art, the PCT publication mentioned by the Examiner is not a new document but a document already contemplated with regard to unity of the invention in the PCT proceedings.

Furthermore, according to MPEP §1850 a detailed discussion of Unity of Invention is made and exemplified by a particular case:

“For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key.”

In fact, some of the prior art documents cited in the International Search Report disclose oral preparations with the same ingredients. However, none of them shows the same ratios. In the present case, the corresponding special technical features are claimed

ratios of components which correspond to the claimed features of an oral preparation that disintegrates quickly. An example of this is set forth in the application as filed and in the wording of Claim 1, wherein it is stated/claimed that the oral preparation of the invention must contain at least 59.5% of spray-dried mannitol. See page 8, lines 24-26, and Claim 1.

The determination whether a group of inventions is so linked as to form a single inventive concept is made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. Thus, Claims 5 to 8 are directed to additional and optional components that could be present in the oral preparation claimed in Claim 1. Claim 12 is directed to a process for obtaining the oral preparation claimed in Claim 1, with or without the additional components claimed in Claims 5 to 8, and therefore is so linked as to form a single inventive concept with Claim 1.

Reconsideration of the restriction requirement and allowance of all the claims herein are respectfully requested.

Respectfully submitted,

William H. Dippert
William H. Dippert
Reg. No. 26,723
For WOLF, BLOCK, LLP

250 Park Avenue, Suite 1000
New York, NY 10177
Telephone: (212) 986-1116
E-mail: pto@wolfblock.com

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/15 03/02446

| | | | |
|-------------------------------------|----------|-----------|-----------|
| A. CLASSIFICATION OF SUBJECT MATTER | | | |
| IPC 7 | A61K9/00 | A61K47/26 | A61K47/38 |
| A61K47/36 | | | |

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, MEDLINE, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
| Y | WO 01 12161 A (NOVARTIS CONSUMER HEALTH SA ;MARTANI ROSA (FR)) 22 February 2001 (2001-02-22) page 11, line 12 - line 28 page 12, line 4 example 1 ---- -/-/ | 1-14 |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

2 October 2003

Date of mailing of the international search report

15/10/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Villa Riva, A

INTERNATIONAL SEARCH REPORT

| | |
|-----------------|------------------|
| -International | Application No.: |
| PCT/IB 03/02446 | |

| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|--|---|-----------------------|
| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| Y | <p>NILSSON P ET AL: "PHYSICOCHEMICAL ASPECTS OF DRUG RELEASE V. THE IMPORTANCE OF SURFACE COVERAGE AND COMPACTION ON DRUG DISSOLUTION FROM ORDERED MIXTURES" INTERNATIONAL JOURNAL OF PHARMACEUTICS (AMSTERDAM), vol. 45, no. 1-2, 1988, pages 111-122, XP009018006 ISSN: 0378-5173 abstract page 112, right-hand column, line 26 -left-hand column, last line table 4 figure 2 page 120, left-hand column, line 24 -right-hand column, line 2</p> <p>MATTSSON S ET AL: "Formulation of high tensile strength rapidly disintegrating tablets: Evaluation of the effect of some binder properties" S.T.P. PHARMA SCIENCES 2001 FRANCE, vol. 11, no. 3, 2001, pages 211-220, XP009018012 ISSN: 1157-1489 abstract page 211, left-hand column, line 28 - last line page 211, right-hand column, line 30 -page 212, left-hand column, line 2 page 212, right-hand column, line 6,22,23 table 3 page 217, Section 3.2 figure 7 page 219, right-hand column, line 28 - line 48</p> <p>US 5 904 937 A (VLADYKA JR RONALD S ET AL) 18 May 1999 (1999-05-18) example 6</p> <p>US 5 686 107 A (RATNARAJ SHEILA ET AL) 11 November 1997 (1997-11-11) preparations 15AA, 3ASP, 7ASP</p> | 1-14 |
| A | | 1-14 |
| A | | 1-14 |

INTERNATIONAL SEARCH REPORT

Internal Application No.
PCT/IB 03/02446

| Patent document cited in search report | Publication date | | Patent family member(s) | Publication date |
|--|------------------|------------|---|--|
| WO 0112161 | A | 22-02-2001 | AU 7275700 A CA 2380449 A1 WO 0112161 A1 EP 1202716 A1 JP 2003506480 T TR 200200313 T2 US 2002131998 A1 | 13-03-2001 22-02-2001 22-02-2001 08-05-2002 18-02-2003 22-04-2002 19-09-2002 |
| US 5904937 | A | 18-05-1999 | AU 1063799 A BR 9812590 A GA 2303177 A1 CN 1273527 T EP 1027038 A1 JP 2001518491 T NO 20001670 A PL 339568 A1 WO 9917748 A1 | 27-04-1999 01-08-2000 15-04-1999 15-11-2000 16-08-2000 16-10-2001 22-05-2000 18-12-2000 15-04-1999 |
| US 5686107 | A | 11-11-1997 | NONE | |

PATENT COOPERATION TREATY

PCT

REC'D 24 SEP 2004

WIPO

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

| | | |
|---|---|---|
| Applicant's or agent's file reference A-156736 | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
| International application No. PCT/IB 03/02446 | International filing date (<i>day/month/year</i>) 04.06.2003 | Priority date (<i>day/month/year</i>) 10.06.2002 |

International Patent Classification (IPC) or both national classification and IPC
A61K9/00

Applicant
LABORATORIOS VITA, S. A.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

- I Basis of the opinion
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

| | |
|--|---|
| Date of submission of the demand 19.12.2003 | Date of completion of this report 23.09.2004 |
| Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Villa Riva, A Telephone No. +49 89 2399-8404 |



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IB 03/02446

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1, 2, 5-10, 12-24 as originally filed
3, 4, 11 received on 29.04.2004 with letter of 26.04.2004

Claims, Numbers

12 (part), 13, 14 as originally filed
1-11, 12 (part) received on 29.04.2004 with letter of 26.04.2004

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 the language of publication of the international application (under Rule 48.3(b)).
 the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

contained in the international application in written form.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority in written form.
 furnished subsequently to this Authority in computer readable form.
 The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

the description, pages:
 the claims, Nos.:
 the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/B 03/02446

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N) Yes: Claims 1-14
 No: Claims

Inventive step (IS) Yes: Claims 1-14
 No: Claims

Industrial applicability (IA) Yes: Claims 1-14
 No: Claims

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB 03/02446

Section V

Reference is made to the following documents:

D1 - WO0112161, disclosing fast disintegrating tablets

D2 - NILSSON P ET AL: "PHYSICOCHEMICAL ASPECTS OF DRUG RELEASE V. THE IMPORTANCE OF SURFACE COVERAGE AND COMPACTION ON DRUG DISSOLUTION FROM ORDERED MIXTURES" INTERNATIONAL JOURNAL OF PHARMACEUTICS (AMSTERDAM), vol. 45, no. 1-2, 1988, pages 111-122

disclosing drug release in quick disintegrating tablets as a function of the choice of excipients, surface and compaction;

D3 -MATTSSON S ET AL: "Formulation of high tensile strength rapidly disintegrating tablets: Evaluation of the effect of some binder properties" S.T.P. PHARMA SCIENCES 2001 FRANCE, vol. 11, no. 3, 2001, pages 211-220, disclosing ternary mixtures with compound, microcrystalline cellulose and superdisintegrant

D4 - US5904937, disclosing taste masked oral admin forms with microcrystalline cellulose,

D5 - US5686107, disclosing tablets with improved texture and taste

Although some of the cited prior art documents disclose oral preparations with the same ingredients, none of them shows the same ratios . Insofar the subject-matter of present claims 1-14 can be considered novel as required by the PCT Art. 33(1) and (2).

D1, which is the closest prior art, discloses the same combination of ingredients in claim 14 (at least from a qualitative point of view) as in present claim 1; the difference is that claim 14 is silent about the amounts of said ingredients. It is also silent on the point whether mannitol is spray-dried or prepared according to another technique.

Therefore, it would not be considered obvious for the skilled person to choose spray-dried mannitol or the ratios of claim 1; the presence of an inventive step can be acknowledged under Art. 33(1) and (3) PCT.